K122567

JUN 19 2013

Attachment IV

510(k) Summary

Submitter:	Sciton, Inc.
Address:	925 Commercial Street, Palo Alto, CA 94303
Phone:	(650) 493-9155
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Contact Person:	Jay M. Patel, VP of Regulatory Affairs
Date Prepared:	June 17, 2013
Device Trade Name:	JOULE 810/940/980 Multi-Platform System
Common Name:	Laser Powered Surgical Device (and Accessories)
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Legally Marketed Predicate Device:	K112031: Alma Lasers Modified Diode Laser Module K102036: LAMBDA S.p.A. Doctor Diode Laser Family K100558: Quanta System QUANTA Diode Laser Family K100143: CAO Group Pilot Diode Laser K053628: Lumenis LightSheer Duet
Description of JOULE 810/940/980 Multi-Platform System:	The JOULE 810/940/980 Multi-Platform System consist of a console and laser deliver accessories. It uses focusing optics to deliver thermal energy to the treatment site. The control console houses the power supply, cooling system, articulated arm delivery system and/or fiber optic arm delivery system with a handpiece. The user activates laser emission by means of a footswitch.
Intended Use:	The JOULE 810/940/980 Multi-Platform System (and delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue. The device is specifically indicated for use as follows: **810nm and 980nm** **Dermatology/Aesthetics:** - Photocoagulation of vascular & dermatological lesions of the face and extremities - Photocoagulation of telangiectasia, veinulectasia of the legs and face - Treatment of reticular veins and branch varicosities - Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas - Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi. - Dermatological surgery: Condyloma acuminate, warts, small non malignant skon tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridment.

- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

Plastic Surgery:

- Cut, coagulation & vaporization
- Resurfacing
- Blepharoplasty

Vascular Surgery:

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

810nm

Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.
The JOULE Multi-Platform System is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudofolliculitis barbae. It is also indicated for hair removal, permanent hair reduction, and the treatment of benign pigmented lesions and leg veins. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

940nm

The JOULE Multi-Platform System (and their delivery accessories used to deliver optical energy) are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, and for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

980nm

The JOULE Multi-Platform System (and their delivery accessories used to deliver optical energy) is indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue endovenous occlusion of the greater saphenous vein. The JOULE 980 System is further indicated for laser assisted lipolysis.

The device is specifically indicated for use as follows:

Dermatology, Plastic Surgery and Podiatry:

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, skin, fat or muscle tissue and dermabrasion. Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Excision of cutaneous lesions
- Dermabrasion
- Vaporization and hemostasis of capillary hemangioma
- Debridement of wounds
- Photocoagulation of teleangectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities

- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.
- Treatment of reticular veins and branch varicosities

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux:

Indicated for use with their delivery accessories in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

Technological Characteristics:	The JOULE 810/940/980 Multi-Platform System shares the same indications for use, and as noted below, shares similar design features (including wavelength, laser medium and delivery systems, power supply, cooling and control system), functional features (including power output, repetition rate, energy, spot size and fluence), and is therefore substantially equivalent to the above legally marketed predicate devices.

JOULE 810/940/980 Multi-Platform System

Specification	This Application	Predicate Devices					Substantially Equivalent
	JOULE 810/940/980 Multi-Platform System	Alma Lasers Modified Diode Laser Module	LAMBDA S.p.A. Doctor Diode Laser Family	Quanta System QUANTA Diode Laser Family	CAO Group Pilot Diode Laser	Lumenis LightSheer Duet	
Indications for Use	General surgical applications. Intended for hair removal and treatment for benign pigmented and vascular lesions. Temporary relief of muscle & joint pain due to elevated tissue temperature	General surgical applications. Intended for hair removal and treatment for benign pigmented and vascular lesions.	General surgical applications. Intended for hair removal and treatment for benign pigmented and vascular lesions.	General surgical applications. Intended for hair removal and treatment for benign pigmented and vascular lesions.	General surgical applications. Temporary relief of muscle & joint pain due to elevated tissue temperature.	General surgical applications. Intended for hair removal and treatment for benign pigmented and vascular lesions.	Yes
Ref. 510(k)	N/A	K112031	K102036	K100558	K100143	K053628	--
Wavelength	810, 940 & 980 nm	810 nm	810, 940, 980 & 1064 nm	532, 810, 940, 980, 1064, 1320, 1470, 1950 nm	810 nm	790 - 950 nm (800 nm nominal)	Yes
Fluence	≤ 120 J/cm2	≤ 120 J/cm2	--	--	--	10 - 100 J/cm2	Yes
Max Power	≤ 100 W	≤ 100 W	≤ 15 W	≤ 30 W	≤ 15 W	1600 W peak power	
Pulse Duration	≤ 2500 msec	≤ 1350 msec	--	≤ 2500 msec	--	5 - 400 msec	Yes
Spot Size	0.6mm Ø to 7.7 cm2	1.2 cm2	--	0.6 - 2.4 mm Ø	--	22x35mm (7.7 cm2)	Yes
Output Mode	CW & pulsed mode	CW & pulsed mode	CW & pulsed mode	CW & pulsed mode	CW & pulsed mode	CW & pulsed mode	Yes
Repetition Rate	≤ 200 Hz	≤ 10 Hz	--	≤ 200 Hz	2.5 - 20,000 Hz	≤ 3 Hz	Yes
Laser Type	Diode	Diode	Diode	Diode	Diode	Diode	Yes
Electrical Requirements	230 VAC, 50/60 Hz, 1Φ	120/230 VAC, 50/60 Hz, 1Φ	--	100-200VAC, 50/60Hz, 1Φ	--	110 - 240VAC 50/60 Hz, 1 Φ	Yes
Console Dimensions	16" x 30" x 43" high	20" x 23" x 47" high	--	16" x 13" x 10" high	--	17" x 20" x 44" high	Yes
Delivery System	Fiber optic with handpiece	Fiber optic with handpiece	Fiber optic with handpiece	Fiber optic with handpiece	Fiber optic with handpiece	Fiber optic with handpiece	Yes
User Interface	LCD touchscreen	LCD touchscreen	LCD touchscreen	LCD touchscreen	LCD touchscreen	LCD touchscreen	Yes

Safety and Effectiveness:	The indications for use are based upon the indications for use for predicate systems. Technologically, the JOULE 810/940/980 Multi-Platform System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the JOULE 810/940/980 Multi-Platform System are comparable to the predicate devices.
Conclusion:	JOULE 810/940/980 Multi-Platform System shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 19, 2013

Sciton, Inc.
% Mr. Jay M. Patel
925 Commercial Street
Palo Alto, California 94303

Re: K122567
Trade/Device Name: Joule 810/940/980 Multi-Platform System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 31, 2013
Received: June 04, 2013

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment III

Statement of Indications for Use

510(k) Number (if known): K122567

Device Name: JOULE 810/940/980 Multi-Platform System

Indications for Use:

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The device is specifically indicated for use as follows:

810nm and 980nm

Dermatology/Aesthetics:

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminate, warts, small non malignant skon tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridment.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

Plastic Surgery:

- Cut, coagulation & vaporization
- Resurfacing
- Blepharoplasty

Vascular Surgery:

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

Prescription Use X OR Over-The-Counter Use _____
(Per 21CFR801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.06.18 16:11:45 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K122567

810nm

Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.

The JOULE Multi-Platform System is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudofolliculitis barbae. It is also indicated for hair removal, permanent hair reduction, and the treatment of benign pigmented lesions and leg veins. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

940nm

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Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21CFR801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.06.18 16:12:16 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K122567

980nm

The JOULE Multi-Platform System (and their delivery accessories used to deliver optical energy) is indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue endovenous occlusion of the greater saphenous vein. The JOULE 980 System is further indicated for laser assisted lipolysis.

The device is specifically indicated for use as follows:

Dermatology, Plastic Surgery and Podiatry:

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, skin, fat or muscle tissue and dermabrasion. Examples include:

- Matrixectomy
- Excision of neuromas
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Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux:

Indicated for use with their delivery accessories in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

Prescription Use ____X____ OR Over-The-Counter Use _____
(Per 21CFR801)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.06.18 16:12:47 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K122567